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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/270,910	03/16/99	IPSEN H	4305/1E144-U

HM12/0614

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EXAMINER	
DIBRINO,M	
ART UNIT	**PAPER NUMBER**
1644	9

DATE MAILED: 06/14/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/270,910	Ipsen et al.
Examiner	**Group Art Unit**
Marianne DiBrino	1644

☒ Responsive to communication(s) filed on *Mar 16, 1999*

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *1* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) *1-34 and 40-47* is/are pending in the applicat

Of the above, claim(s) _____ is/are withdrawn from consideration

☐ Claim(s) _____ is/are allowed.

☐ Claim(s) _____ is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims *1-34 and 40-47* are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____ .

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

1. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures.

2. Applicants are required to amend the specification to list the appropriate SEQ ID NOS for sequences disclosed in the specification (for example, Brief Description of the Drawings for Fig. 1-3, 12, page 29, lines 30 and 31). 37 CFR 1.821(d).

3. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

I. Claims 1-28, 32-34 and 47 drawn to a recombinant allergen, and composition, thereof, classified in Class 530, subclass 350 and Class 424, subclass 185.1.

II. Claims 29-31 and 42, drawn to a method of preparing a recombinant allergen and pharmaceutical composition, thereof, classified in Class 435, subclass 69.1.

III. Claims 40, 41, 43-46, drawn to a method of treating, vaccinating or preventing allergic reactions in a subject by administering a recombinant allergen or composition, thereof, classified in Class 424, subclass 275.1.

4. Inventions I and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)).

In the instant case, the product as claimed can be used in a materially different process such as immunopurification procedures or diagnostic assays.

5. Inventions II and III are different methods.

These inventions require different ingredients and process steps to accomplish either making a recombinant allergen or treating/preventing an allergic reaction in a subject.

6. Inventions II and I are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (M.P.E.P. § 806.05(f)).

In the instant case, the recombinant allergen and pharmaceutical composition, thereof, can be made by scanning mutagenesis.

Therefore, they are patentably distinct.

7. Because these inventions are distinct for the reasons given above and the search required for any group from Groups I-III is not required for any other group from Groups I-III and Groups I-III have acquired a separate status in the art as shown by their different classification.

8. **If Applicant elects the Invention of Group I**, Applicant is further required to (1) elect a single disclosed species (a ***specific recombinant allergen and pharmaceutical composition, thereof***, from a **specific allergenic protein** from **a specific taxonomic order** and **a specific animal** (if it is an animal allergen) comprising **a specific set of substitutions**, for example, a venom allergen from Apidae with a substitution of Lys72Ala) to which claims would be restricted if no generic claim is finally held to be allowable and (2) to list all claims readable thereon including those subsequently added.

These species are distinct because their structures and physico-chemical properties are different.

9. **If Applicant elects the Invention of Group II**, Applicant is further required to (1) elect a specific method of preparing a recombinant allergen comprising preparing a ***specific recombinant allergen and pharmaceutical composition, thereof***, from a **specific allergenic protein** from **a specific taxonomic order** and **a specific animal** (if it is an animal allergen) comprising **a specific set of substitutions**, for example, a venom allergen from Apidae with a substitution of Lys72Ala) to which claims would be restricted if no generic claim is finally held to be allowable and (2) to list all claims readable thereon including those subsequently added.

These methods are distinct because their starting materials, endpoints, and steps are different and result in recombinant allergens with different structures and physico-chemical properties.

10. **If Applicant elects the Invention of Group III**, Applicant is further required to (1) elect a a specific method of treating, vaccinating or preventing an allergic response comprising administering a ***specific recombinant allergen and pharmaceutical composition, thereof***, from a **specific allergenic protein** from **a specific taxonomic order** and **a specific animal** (if it is an animal allergen) comprising **a specific set of substitutions**, for example, a venom allergen from Apidae with a substitution of Lys72Ala) to which claims would be restricted if no generic claim is finally held to be allowable and (2) to list all claims readable thereon including those subsequently added.

These methods are distinct because they administer different recombinant allergens with different structures and physico-chemical properties.

11. Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

12. Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

13. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. § 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. M.P.E.P. § 809.02(a).

14. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

15. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

16. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marianne DiBrino whose telephone number is (703) 308-0061. The examiner can normally be reached Monday through Friday from 8:30 am to 6:00 pm. a message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Marianne DiBrino

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June 12, 2000

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